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K122516

FEB 2 1 2013

510(K) SUMMARY

SUBMITTER INFORMATION

A. Company Name: Embla Systems

B. Company Address: Embla Systems
1 Hines Road, Suite 202
Kanata, Ontario
K2K 3C7 Canada

C. Company Phone: (613) 254-8877

D. Company Facsimile: (613) 270-0627

E. Company Contact: Jennifer Armstrong
Manager, Regulatory Affairs
E-mail: Jennifer.armstrong@embla.com

PREPARATION DATE

August 3, 2012
Revised: January 23, 2013

DEVICE IDENTIFICATION

A. Device Trade Name: Embletta MPR Sleep Data Recording System

B. Device Common Name: Embletta MPR

C. Classification Name: Breathing frequency monitor

D. Regulation Number: 21 CFR 868.2375

E. Product Code: MNR

F. Device Class: Class II

PREDICATE DEVICES

A. Trade Name: Embla Compass, 510(k) Number: K041904
B. Trade Name: Embletta Gold, 510(k) Number: K073682

DEVICE DESCRIPTION

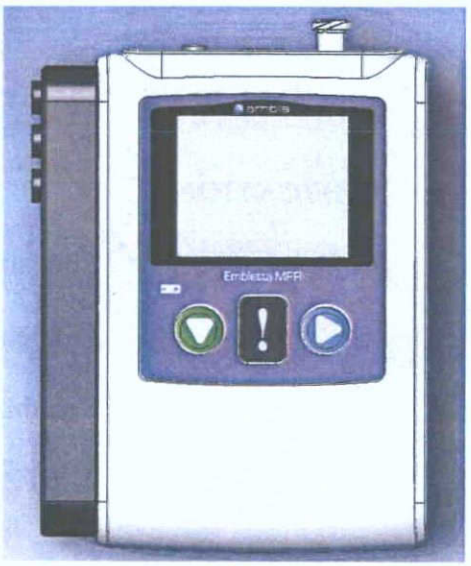
The Embletta MPR Sleep Data Recording System is the third in the Embla series of small ambulatory sleep recorders. The first was the Embla Compass (also called the Embletta, K041904, Product Code MNR) and the second is the Embletta Gold (K073682, Product Code MNR).

The Embletta MPR Sleep Data Recording System records multiple physiological parameters for the purpose of simultaneous or subsequent uploading to a separate PC based data presentation software. The data collected by this recording system will provide physicians with information to make a sleep disorder diagnosis.

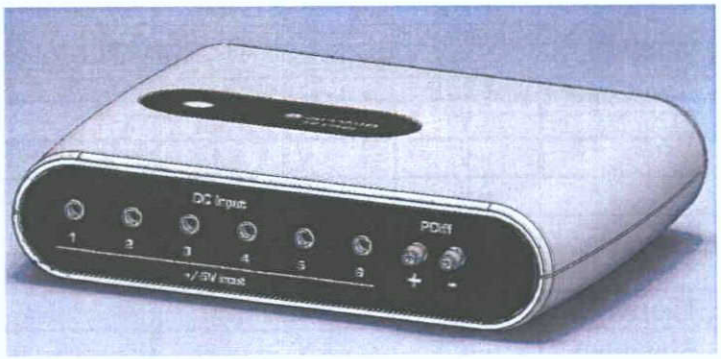
The Embletta MPR Sleep Data Recording System consists of three small devices that can be used in two separate configurations. The simplest configuration is the battery operated Embletta MPR recorder which is worn by the patient and used alone for small scale sleep studies (2 input + 3 derived channels). The other configuration is the battery operated Embletta MPR 'PG' unit (similar to the Embletta MPR but with 6 input + 3 derived channels) which is worn by the patient and used with wireless communication to a separate mains powered Embletta 'TX' unit located remotely from the patient. The Embletta 'TX' unit can also record inputs from separate patient devices (such as CPAP devices).

Embletta MPR

Embletta MPR 'PG'



TX Proxy



Each of these two configurations basically consists of a simple signal recording unit that can be connected with several electrodes and sensors non-invasively attached to a patient during sleep. The Embletta MPR and the Embletta MPR 'PG' are secured to the patient with a belt and holder.

INTENDED USE

The Embletta MPR (**M**ultiple **P**arameter **R**ecorder) Sleep Data Recording System is a digital recording system designed to be used under the direction of a physician or trained technician or applied by a layperson under the direction of a physician or trained technician.

The system records multiple physiological parameters for the purpose of simultaneous (on-line recording) or subsequent (ambulatory recording) uploading to a separate PC based data presentation software for graphical and numerical representation to allow trained personnel to identify sleep disorders. The data collected by this recording system will provide physicians with information to make a diagnosis of sleep disorders such as:

Disorder	Compass (Embletta)	Embletta Gold	Embletta MPR
• Obstructive Sleep Apnea Syndrome	√	√	√
• Central Alveolar Hypoventilation Syndrome	√	√	√
• Central Sleep Apnea Syndrome	√	√	√
• Restless Legs Syndrome	√	√	√
• Periodic Limb Movement Disorder	√	√	√
• Primary Snoring	√	√	√
• Sleep-Related Neurogenic Tachypnea	√	√	√
• Cheyne-Stokes-Breathing	√	√	√

The system has 6 - 19 channel capability for recording signals:

Recorded channels:	MPR	MPR 'PG'	TX Proxy
	Used alone	Used together	
• Pressure	√	√	
• Oximetry	√	√	
• Audio	√	√	
• EKG, EEG, EMG		√	
• Thermister		√	
• Respiration, Thorax		√	
• Respiration, Abdomen		√	
• DC channel		1	6
• Therapy devices			√
• Differential pressure			√
Derived channels:			
• Snore	√	√	
• Actigraphy	√	√	
• Body Position	√	√	

The general intended environments are hospitals, institutions, sleep centers, the home and sleep clinics or the patient's home. The studies will be supervised by trained physicians, trained sleep technicians (RPSGT) or clinicians. The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

The Embletta MPR unit is intended for ambulatory or patient in-home studies while the Embletta MPR PG and TX Proxy units are intended for ambulatory, patient in-home studies and clinic on-line studies.

The Embletta MPR system is intended to be used for adult and pediatric (excluding neonatal and infant) studies.

The recorder does not provide any alarms and is not intended to be a life monitor.

INDICATIONS FOR USE (Embletta MPR)

The Embletta MPR is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The Embletta MPR records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel.

The Embletta MPR is intended to be used for adult and pediatric (excluding neonatal and infant) studies. The device is not equipped with alarms and is not intended to be used as a monitor.

The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

The device does not monitor or diagnose the patient and does not issue any alarms.

INDICATIONS FOR USE [Embla Compass (Embletta) predicate device]

The intended use of the Compass F10 system is to record physiological signals during sleep, scan the signals for abnormalities and represent the count of abnormal events in a form of a summary report. The results of the scan may be manually overwritten or corrected by the physician. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's count of abnormal events. It is not intended for any diagnosis. It is not intended to be a monitor.

The Compass F10 device is intended to be used for adult and pediatric patients.

INDICATIONS FOR USE (Embla Embletta Gold predicate device)

The Embletta Gold is a digital recording device designed to be used under the direction of a physician or trained technician but applied by a lay person. The Embletta Gold records multiple physiological parameters for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel.

The Embletta Gold is intended to be used for adult and pediatric (excluding neonatal and infant) studies. Note the recorder is not equipped with an alarm device and is not intended to be used as a life monitor.

The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

COMPARISON TO PREDICATE DEVICES

The Embletta MPR Sleep Data Recording System is the third in a series of Embla ambulatory sleep data recorders. It is substantially equivalent in the following technological ways to the intended use and application to the two previous versions, the identified predicate devices;

Note	Parameter	Embla Compass (Embletta)	Embletta Gold	Embletta MPR
	510(k) #	K041904	K073682	TBD
	Product Code	MNR	MNR	MNR

1	Intended use*	Equivalent	Equivalent	Equivalent
1	Indications for Use	Equivalent	Equivalent	Equivalent
2	Target Population	Adult and pediatric patient groups	Adult and pediatric patient (excluding neonatal and infants)	Adult and pediatric patient (excluding neonatal and infants)
	Where Used	Sleep clinics and home	Sleep clinics and home	Sleep clinics and home
	Energy Used	Battery operated (2 AA)	Battery operated (2 AA)	Battery operated (2 AA)
	Human factors:			
3	• Device setup	Similar (PC)	Similar (PC)	Similar (PC)
4	• Electrode application	Identical	Identical	Identical
5	Design	Signal sensing, conditioning, noise filtering, amplification and recording.	Identical	Identical
6	Performance:			
	• Recording Time	72 hours	48 hours	24 hours (200 total hrs)
	• Data Interface	USB	USB	USB
	• # of Channels	Depends on proxy	8 + 3 derived	16 + 3 derived
	EKG	√	√	√
	EEG	√		√
	EMG	√		√
	EOG	√		
	Pulse	√		
	Respiration (Ab)	√	√	√
	Respiration (Th)	√	√	√
	Thermistor		√	√
	Oximetry	√	√	√
	Pressure	√	√	√
	Dif. Pressure		√	√
7	Actigraphy (derived)	√	√	√
7	Body Position (derived)	√	√	√
7	Snore (derived)	√	√	√
8	DC Auxiliary		1	7
9	(C,V) PAP			√

10	Audio			√
	Standards met	Same	Same	Same
	Materials	Non-metallic	Non-metallic	Non-metallic
	Biocompatibility	N/A, worn over clothes	N/A, worn over clothes	N/A, worn over clothes
	Sterility	Not sterile	Not sterile	Not sterile
	Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1
	Handheld	Yes	Yes	Yes
	Weight	146g	190g	136g

NOTES:

1. Indications for use and Intended use – The Embla Compass (Embletta) and Embletta Gold predicate devices are small palm-size portable devices that connect to one or more probes or sensors on the patient to record a variety of physiological signals. This data is then downloaded into a separate computer application software that presents the signals in a format that can be read by a trained technician or physician. This is an identical application of the Embletta MPR.
2. Target Population – The target population for the Embletta MPR is identical to the Embla Compass (Embletta) device: Adult and pediatric patient groups. This is not an expansion of patient groups.
3. Device Setup – All three devices are setup thru the use of a separate application software in an identical fashion. Channels are configured and identified, sampling rates are set, filtering options defined, recording timing (on/off times), etc.
4. Electrode Application – All three devices use commercially available electrodes, cannulas, and thermistors. All three use the separate Embla XactTrace belts for thorax and abdomen respiration sensing. All three can use the separate Nonin XPOD oximetry devices.
5. Design – All three have similar design strategies, different in the level of technology used (with age). All three include basic signal sensing, conditioning, noise filtering, amplification and recording.
6. Performance – Channel options are listed in the table. Channel specifications are essentially identical to predicate device specifications.
7. Derived Channels – The Actigraphy and Body Position channels are derived in the separate software application using the basic X, Y and Z position data from the integrated gravity sensors in all three devices. The Snore channel is derived in the separate software application using the pressure channel from the patient mask with frequency filtering in all three devices.
8. DC Auxiliary Channels – Due to increased user requests for channels to record external +/- 5 Vdc signals, the Embletta MPR has additional (7) DC Auxiliary channels that can be identified and configured by the separate application software (usually flow, pressure, leak information, depending on the therapy systems additionally information about tidal volume, respiratory rate, inspiratory pressure, target pressure).

9. (C,V) PAP – The Embletta MPR can accept data from therapy devices. This is a new feature for an ambulatory recording device not present in the two predicate devices.
10. Audio – The Embletta MPR has an audio channel to permit communications from a control room location to the patient or a clinician with the patient. This is a new feature not present in the two predicate devices.

TESTING AND PERFORMANCE DATA

The design input requirements for the Embletta MPR were created from, and based on predicate device specifications and functionality, adjusted and revised in accordance with new marketing requirements and current state of the art technology. Testing included the following:

1. Verification testing in the design stages. This testing consisted of verification of engineering specifications derived from the design input requirements. The document "Verification Protocols" and "Verification Report" have been submitted.
2. Validation testing after design completion. This testing consisted of validation of each design input requirement in a production equivalent system setting. The document "Validation Test Plan", "Validation Test Protocols" and "Validation Report" have been submitted.
3. Electrical Safety testing – Safety tests have been performed to verify compliance with IEC 60601-1 and the applicable particular standards listed below to ensure that there are no potential hazards on patients, operators, or the surroundings.
4. Electromagnetic Compatibility testing –
    a. Electromagnetic Compatibility tests have been performed to verify compliance with IEC 60601-1-2 to ensure that no intolerable electro-magnetic disturbances are introduced.
    b. Immunity tests have been performed to verify compliance with IEC 60601-1-2 to ensure that the device operates satisfactorily in an electromagnetic environment.

Medical Electrical Equipment: General Requirements for Safety.	IEC 60601-1: 2001 2nd ed.
Electromagnetic Compatibility –Requirements and Tests	IEC 60601-1-2: 2001 2nd ed.
Particular Requirements for the Safety of Electrocardiographs	IEC 60601-2-25:1993
Particular Requirements for the Safety of Electroencephalographs	IEC 60601-2-26:1994
Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment	IEC 60601-2-40:1998

CONCLUSION

We believe that the results of the performance testing for the Embletta MPR Sleep Data Recording System, as well as the substantial equivalence comparison to the two predicate devices, are adequate to support a conclusion for the safety and efficacy of the device,

Based on the test results and the substantial equivalence comparison, it is the conclusion of Embla Systems that the Embletta MPR Sleep Data Recording is substantially equivalent to devices already on the market and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Ms. Jennifer Armstrong
Embla Systems
Manager, Regulatory Affairs
1 Hines Road, Suite 202
Kanata, Ontario
Canada K2K 3C7

Re: K122516
Trade/Device Name: Embletta MPR Sleep Data Recording System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: January 24, 2013
Received: January 31, 2013

Dear Ms. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MA
Mary S. Runner
2013.02.21
12:11:51 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

January 23, 2013

SECTION 6

STATEMENT OF INDICATIONS OF USE

510(k) Number (if known): Unknown

Device Name: **Embletta MPR Sleep Data Recording System**

Indications For Use:

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The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.

The device does not monitor or diagnose the patient and does not issue any alarms.

Prescription Use __X__ AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
Division Sign-Off
2013.02.21 11:06:09 -05'00'
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122516